CES 363

Compulsory Ethiopian Standard

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Pharmacy – Requirements

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Foreword

This Ethiopian Standard has been prepared under the direction of the Technical Committee for Essential Drugs (TC 88) and published by the Institute of Ethiopian Standards (IES).

Application of this standard is COMPULSORY with respect to clauses 4 and 5. A Compulsory Ethiopian Standard shall have the same meaning, interpretation and application of a "Technical Regulation" as implied in the WTO-TBT Agreement.

Implementation of this standard shall be effective as of 09/01/2024.

Pharmacy – Requirements

1. Scope

The standard specifies requirements concerning practices, premises, professionals and products (equipment and materials) used in pharmacies. It applies to both new and existing pharmacies across the country, irrespective of ownership. However, this requirement does not apply to pharmacy services included as a part of health facilities services.

2. Normative reference

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
No normative reference is used for this document.

3. Terms and definitions

For the purpose of this requirement the following terms and definitions shall apply.

3.1.

pharmacy

a private, government or non-government owned community pharmacy led by a registered and licensed pharmacist to provide pharmaceutical care and dispense medicines to consumers.

3.2.

Community pharmacy

a licensed pharmacies and drug shops that provide pharmacy services where pharmacy professionals directly in contact with patients and dispense medicines with monitoring drug therapy. Dispensing of medicine may be either on prescription order or over-the-counter.

3.3.

regional or city administration health regulatory body

a state or city administration government organ authorized to implement food, medicine and healthcare administration and control activities at a state or city administration level;

3.4.

authority

the Ethiopian Food and Drug Authority

3.5.

proclamation

the Food and Medicine Administration Proclamation No. 1112/2019

3.6.

appropriate law

a law issued by a state or city administration to implement regulatory activities regarding food, medicine and healthcare services.

3.7.

person

any physical or juridical person

3.8.

authorized person

any pharmacy staff member responsible for providing services

3.9.

Certificate of competence

a permit issued to a person to carry out pharmacy services at community pharmacy level as stated under the proclamation No 1112/2019 and this standard.

3.10.

compounding

the process of preparing extemporaneous medicines for individual patients, in accordance with a written prescription.

3.11.

good pharmacy practice

pharmacy practice that meets the needs of the people who use the services, providing optimal, evidence-based care.

3.12.

owner

person who owns the pharmacy

3.13.

technical manager

a licensed pharmacist who is either an owner or appointed by the owner to have authority over and be responsible for the operation of the pharmacy and named in the certificate of competence issued by regional or city administration regulatory body for the pharmacy as the manager;

3.14.

pharmacy professional

a pharmacist, druggist or pharmacy technician licensed by an appropriate health professional regulatory organ.

3.15.

hazardous substance

a substance that poses substantial or potential threats to public health or the environment ignitability, reactivity, corrosiveness and toxicity;

3.16.

medicines waste

waste which encompass the following:

a) All properly unsealed bulk products or loose tablets and capsules. If unexpired these shall only be used when the container is still sealed, properly labeled or still within the original unbroken blister packs,
b) All cold chain damaged, unexpired medicines that should have been stored in a cold chain but were not,
c) Counterfeit, substandard and adulterated,
d) Discarded items used in the handling of medicines,

e) Expired, unused, spilt, and contaminated,

f) Improperly sealed or labeled or stored,

g) Expired, damaged, and improperly sealed or labeled or stored laboratory reagents,

h) Expired, damaged, and improperly sealed or stored medical supplies;

i) Prohibited or unauthorized medicines,

j) Expired, damaged, and improperly sealed or labeled or stored raw materials, and

k) Discarded packing materials.

3.17.

package

the immediate container or wrapping in which any preparation is contained for use or storage;

3.18.

Self-contained

containing in oneself all necessary service rooms and that do not connect with other service room using doors and windows. This does not include common stairs.

3.19.

label

any material which is printed or affixed to a packing material which provides the necessary information about medicine, and includes an insert;

3.20.

prescription

a paper or electronic order for medicine that meets requirements set by the authority, and written and signed by a duly licensed medical professional and issued to patients to collect medications.

3.21.

active ingredient

any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease.

3.22.

drug Information

written and/or verbal information about pharmaceuticals and the therapeutic use of medicines.

3.23.

drug information service

the provision of up-to-date, unbiased, well referenced, and critically evaluated therapeutic, and pharmaceutical information, including education, training and research.

3.24.

drug information center

a unit designated for providing medicine information services.

4. General requirements

4.1. Any person who wants to operate as a pharmacy shall first obtain a certificate of competence from the appropriate regulatory body.

4.2. The pharmacy shall procure medicines from licensed manufacturers, importers or wholesalers.

4.3. The pharmacy and pharmacy professionals working therein shall be responsible for preventing and reporting suspected substandard and falsified (SF) medicines.

4.4. The pharmacy shall not operate without a registered and licensed pharmacist.

4.5. The pharmacy practice, at all times, shall consistently strive towards higher standards of practice, for the benefit of the patients and community being served.

4.6. The pharmacy professionals shall keep their knowledge current with evidence-based information.

4.7. The pharmacy shall only engage in activities within its legal scope permitted by law and shall implement good pharmacy practices.

4.8. Health promotion and prevention programs permitted in pharmacy shall deliver its intended benefits for the community in promoting wellbeing, reducing preventable illness and lowering overall health care expenditures.

4.9. A pharmacy shall not engage in the wholesale trade of medicines.

5. Specific Requirements

5.1. practices

5.1.1. Prescription

5.1.1.1. A prescription shall be required for dispensing medicines except over the counter medicines as specified by the authority.

5.1.1.2. Patients shall have the right to receive a print out of an electronic prescription, sealed by the health institution.

5.1.1.3. The prescription paper shall contain the following information (Annex A: standard prescription paper).

a)Serial number

b)Name and address of health institution

c)Patient information details: name of patient, gender, age, body weight, height, card number, contact telephone number

d)Area of clinical service: Inpatient, Outpatient, Emergency

e)Diagnosis or International Classification of Disease (ICD) number

f) R_x (Treatment)

g)Prescribed medicine details: name, dosage form, strength, route of administration, dose, frequency and duration of use

h)If the medicine is compounded, name of the active ingredients, dosage type, posology

i) Prescriber and dispenser details: name, and qualification, registration number, signature, stamp and date of prescription and dispensing respectively

5.1.1.4. The pharmacy shall prepare and use its own transcription paper for transcription as specified in Annex B.

5.1.1.5. The pharmacy professionals in the pharmacy shall issue transcription papers to patients for medicines listed in the original prescription but not available in the pharmacy.

5.1.1.6. A special prescription paper shall be required to dispense narcotic drugs or psychotropic substances.

5.1.1.7. The red prescription paper for narcotic drug and blue prescription paper for psychotropic substance shall be used to dispense narcotic drugs or psychotropic substances respectively.

5.1.1.8. Dispensing more than one narcotic drug or psychotropic substance from one prescription paper shall be prohibited.

5.1.1.9. Prescription papers shall be valid for 30 days from the date of prescription, and 15 days for narcotic drugs or psychotropic substances.

5.1.2. Dispensing

5.1.2.1. The pharmacy shall not dispense any medicine without prescription. This shall not include over the counter medicines.

5.1.2.2. The pharmacy shall establish and implement Standard Operating Procedure (SOP) for dispensing practice to ensure patient safety and rational medicines use. This SOP shall include:

a) Receiving a prescription
b) Evaluation and interpretation of a prescription
c) Selecting and preparing the medicines
d) Labeling and packaging the medicines
e) Provision of information and instruction
f) Recording transactions
g) Issuing medicines to the patient

5.1.2.3. The pharmacy shall have standard operating procedure to control the dispensing of narcotic drugs and psychotropic substances, in accordance with relevant laws.

5.1.2.4. The pharmacy professional shall not dispense expired, damaged, substandard, diverted or illegal medicines.

5.1.2.5. The pharmacy professionals shall ensure that prescriptions are legal, legible, complete, and signed by an authorized prescriber.

5.1.2.6. The pharmacy professional shall verify correctness of prescriptions regarding appropriateness for patient, dosage, frequency, duration, route of administration , drug interactions, contraindication, polypharmacy, and inappropriate therapy, based on approved standard treatment guidelines and/or accepted national or international guidelines, before dispensing.

5.1.2.7. The pharmacy professional shall consult the prescriber if he/ she is in doubt regarding the prescription or suspicion of error without causing doubts in the patient.

5.1.2.8. Pharmacy professionals are legally entitled to substitute generic medicines for brand name products while dispensing of medicines by informing the patient unless specific circumstances indicate otherwise.

5.1.2.9. After dispensing medicine as per article 5.1.2.8, the information provided under the prescription shall be logged into a paper or electronic logbook prepared for this purpose, and the prescription shall be filed after being stamped, named, signed and dated by the dispenser.

5.1.2.10. The containers or packing materials used for dispensing shall be appropriate for the product dispensed and all containers intended for medicine shall be protected and kept free from contamination, moisture and light.

5.1.2.11. Medicines to be dispensed shall be labeled and the labels shall be unambiguous, clear, legible and indelible. The label or sticker shall include the following minimum information:

a) Generic name of the medicine;
b) Name of each active ingredient for compounded preparations;
c) Strength, dose, frequency, duration of administration and total quantity
d) Name of the person for whom the medicines are dispensed;
e) Route of administration tailored to patient or caregiver literacy and language;
f) Name and address of the pharmacy;
g) Date of dispensing;
h) Expiry date/beyond use date, and
i) Special precautions as applicable

5.1.2.12. The labels should be printed. If handwritten, labels shall be neat and legible with clear instruction of use.

5.1.2.13. Dispensed prescriptions shall be signed at time of dispensing and accountability shall be accepted by the dispensing pharmacy professional.

5.1.2.14. Narcotic drugs and psychotropic substances shall be handled by the technical manager in the pharmacy.

5.1.2.15. Narcotic drugs and psychotropic substances shall be dispensed by the technical manager or his/her delegate.

5.1.2.16. The pharmacy professional shall retain records of the following information when dispensing narcotic drugs or psychotropic substances.

a) Name and signature of dispensing pharmacist
b) Date and time of dispensing.
c) Name, strength, and quantity dispensed.
d) Serial number assigned to the particular prescription.

5.1.2.17. The pharmacy professionals shall not dispense narcotic drugs or psychotropic substances to patients below the age of 18 years directly, but rather to their caregivers.

5.1.2.18. The pharmacy professionals shall ensure accurate dispensing, reflects the prescriber's intention, and is consistent with the needs and safety of the patient. This includes:

a) Ensuring the correct patient receives the right medicine
b) Avoiding possible interactions.
c) Maintaining the quality and integrity of the medicine throughout the indicated shelf life.
d) Providing clear and correct usage instructions for optimal patient benefits
e) Informing the patients about any special instructions, warnings, potential side effects, and actions in case of adverse events.

5.1.2.19. The pharmacy professionals shall obtain personal details and complete medication history from the patient and/or where appropriate from document reviews.

5.1.2.20. The pharmacy professional shall have a right to refuse dispensing of medicines under considerations such as:

a) Doubts on the prescription or prescribed medication
b) Lack of patient disclose of his/her medical history
c) Illegible prescription handwriting

d) Safety concerns about the prescribed medicine
e) Ineffectiveness concerns for the indicated diagnosis
f) Lack of clear indication for the indicated diagnosis

5.1.2.21. The pharmacy professionals shall contact the prescriber for clarification on prescriptions or patient's therapy when necessary.

5.1.2.22. The pharmacy professional shall update the patient medication history during dispensing for patients with chronic disease.

5.1.2.23. Medicine shall be dispensed in the original primary packaging (i.e. blister or foil packs), except in particular cases where repacking is required to assist patients.

5.1.2.24. Open or split packs shall be clearly marked, and avoid mixing of stock of the same product.

5.1.2.25. To minimize dispensing errors, similarly packaged medicine shall not be stored adjacent to each other on the dispensary shelf.

5.1.2.26. The pharmacy professional shall not promote and advertise in the pharmacy except in legally permitted situations.

5.1.3. Medicine Use Counseling and Drug Information Service

5.1.3.1. Standard operating procedure for medication use counseling shall be prepared and implemented to ensure patient safety and rational use of medicines.

5.1.3.2. The pharmacy professionals shall maintain confidentiality of patient information.

5.1.3.3. The pharmacy professionals shall provide verbal and/or written information to patients to ensure safe and effective use of medicines.

5.1.3.4. Medicine use counseling shall ensure that the patient knows how and when to take the medicines. This includes;

a) Providing extra care in counseling where comprehension may be a problem.
b) Communicating cautionary instructions and ancillary information about medications.
c) Supporting counseling with current, evidence-based information from relevant resources.
d) Tailoring counseling to meet the specific needs of each patient or consumer.
e) Adequately explaining and/or demonstrating the use of medicines to the patient.

5.1.3.5. The drug information service shall include:

a) Production and dissemination of recent medicine information based on scientific and valid references.
b) Providing education about medicine use to clients.
c) managing information queries related to prescribed and OTC medicines
d) Assessing available medicine information and gathering data to address questions/issues
e) Utilize systematic approach to find necessary information
f) Providing guidance on poison management and provision of poison information

5.1.3.6. The drug information service shall not engage in facility, and medicine promotion and advertisement activities.

5.1.4. Good storage practice

5.1.4.1. The pharmacy shall develop and adhere standard operating procedures for good storage practices.

5.1.4.2. The medicine storage room shall be dry, well ventilated and protected from direct sunlight and heat.

5.1.4.3. The medicines storage room shall possess an adequate number and type of shelves to allow orderly storage and adequate segregation of different types of medicines to avoid mix ups.

5.1.4.4. Shelves in the storage room shall be smooth, easily cleanable and impermeable to maintain hygienic conditions.

5.1.4.5. Every medicine shall be stored in accordance with the manufacturer's storage instructions.

5.1.4.6. Light conditions, temperature and humidity within the storage room shall comply with requirements for storage of medicine, raw materials and packaging materials, and shall be monitored regularly.

5.1.4.7. The technical manager or authorized pharmacy professional shall ensure that every key, key card or other device, or the combination of any device, which allows access to a storage room, is kept only on his/her person.

5.1.4.8. Narcotic drugs and psychotropic substances shall be maintained in a securely locked cabinet and access restricted places. After dispensing of narcotic drugs and psychotropic substances, the remaining shall be returned to the cabinet immediately.

5.1.4.9. Chemotherapy agents, biological products, radiopharmaceuticals, narcotics drugs and psychotropic substances, other hazardous, sensitive and/or dangerous pharmaceutical products, as well as other products presenting special risks of abuse, fire or explosion (e.g. combustible liquids, solids and pressurized gases) shall be stored in a dedicated area that is subject to appropriate additional safety and security measures.

5.1.4.10. Medicines that require a cold chain shall be kept in a refrigerator.

5.1.4.11. The temperature of the refrigerator shall be maintained between 2-8 degree celcius

5.1.4.12. The refrigerator shall exclusively be used for storing medicines.

5.1.4.13. The temperature of the refrigerator shall be regularly monitored and recorded twice daily (morning and afternoon) and maintained records.

5.1.4.14. The size of the refrigerator shall enable the pharmacy professional to keep the necessary stock in an organized manner.

5.1.4.15. Medicines shall be arranged on strong and robust shelves made of steel or treated wood or glass.

5.1.4.16. Medicines shall be arranged in shelves according to pharmacological category, alphabetical order by generic name or dosage forms.

5.1.4.17. Medicines shall not be stored directly on the floor without a pallet or shelves.

5.1.4.18. The pharmacy shall segregate expired, damaged and recalled medicines.

5.1.4.19. The pharmacy shall monitor regularly the temperature and humidity of the storage room.

5.1.4.20. The pharmacy professional shall conduct periodic self-assessment audits against the standards.

5.1.4.21. Liquids shall be stored on a pallet or on the lowest level of shelf

5.1.4.22. Flammable substances shall be stored separately

5.1.4.23. Medical devices, cosmetics, baby food (infant formula, follow-up formula, & growing-up formula), food supplements, disinfectants, sanitary and hygiene m aterials shall be kept separately

5.1.4.24. Any return of narcotic drugs or psychotropic substances to the pharmacy shall be documented by the technical manager in the pharmacy by notifying to the authority or regional/city administration health regulatory body.

5.1.5. Good Compounding practice (if compounding is performed in the pharmacy)

5.1.5.1. Standard operating procedures (SOP) for compounding of pharmaceutical preparations shall be established and implemented.

5.1.5.2. The standard operating procedure shall address each process for preparations including receiving raw material, cleaning, dispensing of c ompounded products, method of preparation, and water purification process.

5.1.5.3. The SOP shall contain an approved Master Formula for each type of preparation that shows the list of ingredients and their qua ntities required for the formulation of a specified amount of the preparation.

5.1.5.4. All c ompounding processes shall be in accordance w ith SOPs authorized by the technical manager.

5.1.5.5. Compounding of medicines shall be in accordance with prescription issued by authorized prescriber.

5.1.5.6. Extemporaneous preparations shall only be prepared if there is no equivalent medicine available commercially or the medicine has to be compounded based on the patient's needs.

5.1.5.7. Ingredients for compounding shall be sourced from recognized pharmaceutical suppliers

5.1.5.8. Compounding shall be done by the pharmacist in charge of the pharmacy or pharmacists under his/her direct supervision

5.1.5.9. The phar macist s hall review the ingredients, preparation process, a nd t he intended use of the product, and conduct a risk assessment.

5.1.5.10. The pharmacist shall use pharmaceutical grade ingredients that are stored in accordance with the manufacturer's recommendations.

5.1.5.11. The pharmacist shall ensure that compounding is being carried out in a dedicated room that is clean and suitable for compounding.

5.1.5.12. The pharmacist shall ensure that equipment used in compounding are in good working order.

5.1.5.13. The phar macist s hall ens ure t hat a ll eq uipment an d work surfaces are cleaned bef ore and after compounding.

5.1.5.14. The pharmacist shall ensure that equipment are maintained and calibrated regularly according to a documented procedure.

5.1.5.15. The pharmacist shall document the details of the compounding procedure, compounded products and patient information (Annex C).

5.1.5.16. The pharmacist shall use suitable c ontainers and pac kaging to maintain the quality and stability of prepared products. The containers and container closures shall be made of clean materials that are neither reactive, additive nor absorptive and the packaging shall be appropriate for the stability of the product and proper patient use.

5.1.5.17. The phar macist s hall us e purified water when water is r equired as ingredients i n n on-sterile preparations.

5.1.5.18. Labeling of the compounded products shall provide adequate information including:

a) Preparation Name and strength
b) Total weight or volume of the preparation
c) Name and quantity of each active ingredients
d) Directions for administration and use
e) Storage conditions and special warning/precaution
f) Lot number
g) dosage form
h) name and address of pharmacy
i) Name of compounding pharmacist
j) patient name
k) preparation date
l) beyond use date

5.1.5.19. Standard operating procedures and records shall exist for investigating and correcting failures or problems in compounding, testing, or in the preparation itself.

5.1.5.20. Medicine preparations compounded in the pharmacy shall be packaged in standard containers procured from licensed suppliers.

5.1.6. Clinical pharmacy service

5.1.6.1. The pharmacy professionals should when necessary access physician notes, pat ient diagnoses, or results of medical procedures or laboratory tests upon request.

5.1.6.2. The pharmacy professionals should access patient specific medication therapy information.

5.1.6.3. The pharmacy professionals should provide injectable and non-injectable vaccines specific to adult vaccination when permitted by law.

5.1.6.4. The pharmacist should evaluate patient-specific medication therapy information and develop a medication therapy plan mutually with the patient, and prescriber.

5.1.6.5. The pharmacist shall identify problems or opportunities for optimizing treatment through prescription and medication history monitoring and ensure optimal use of medicines.

5.1.6.6. The phar macy professional should provide Medication T herapy M anagement (MTM) s ervice for chronic illness incorporating the following five core components:

a) Medication Therapy Review (MTR)
b) Personal Medication Record (PMR)
c) Medication-related Action Plan (MAP)
d) Intervention and/or referral
e) Documentation and follow-up

5.1.6.7. The pharmacy professionals shall provide responding to symptoms service in the pharmacy considering, one of three recommendations during each encounter involving symptom presentations:

a) Provide assurance that drug therapy is unnecessary.

b) Suggest treatment with non-drug measures, OTCs, or both.

c) Refer the patient to the appropriate health facility.

5.1.6.8. The pharmacy professional shall be aware of high risk conditions and consider referring the patient to the health facility in case of:

a) Long duration of symptoms.

b) Recurring or worsening problems.

c) Severe symptoms.

d) Failed medication.

e) Suspected adverse drug reactions.

f) Danger symptoms such as blood in the sputum, vomit, urine or feces

5.1.6.9. The pharmacy professional shall involve in signposting and referral to other services and support including:

a) Advising clients about other health and social care providers, and support organizations, when appropriate.

b) Refer the patient when this is felt appropriate by the pharmacy professional.

c) Record the advices or referrals may be made on the patient's pharmacy record, when the pharmacist deems it to be of clinical significance.

5.1.6.10. The pharmacy professional should work with Primary Care Organizations (PCOs), social care providers and other health facilities in their area to facilitate referrals.

5.1.6.11. The pharmacy professional should take appropriate measurements such as weight, height, blood sugar and vital signs for patients with chronic illnesses like hypertension, diabetes and chronic cardiac failure. Maintain logbook for documenting such services.

5.1.6.12. The pharmacy professional shall prevent, detect and respond to drug therapy problems.

5.1.6.13. The pharmacy professional shall take appropriate training to provide clinical pharmacy services and patient measurements.

5.1.7. Procurement and stock management

5.1.7.1. The pharmacy shall develop and implement standard operating procedure for procurement, stock management, storage, return and recall of medicines.

5.1.7.2. The pharmacy shall be obliged to avail essential medicines for the local community.

5.1.7.3. The pharmacy shall hold medicines as per the lists of medicines for pharmacy.

5.1.7.4. The technical manager or his/her delegate shall procure medicines for the pharmacy.

5.1.7.5. Medicine procurement for chain pharmacies shall be made at headquarters of the pharmacy. Each branch pharmacies shall submit procurement need, receive internal transfer vouchers and keep copies of procurement documents.

5.1.7.6. The pharmacy shall obtain medicines from licensed manufacturers, importers or wholesalers.

5.1.7.7. The pharmacy shall procure medicines that are registered or authorized by the authority.

5.1.7.8. When receiving medicines, the pharmacy shall

a) Inspect the medicine for any damages and ensure that original containers are unopened and in good condition

b) Check for expired medicines

c) Separate and quarantine defective stock.

d) Dispose of unfit for use medicines using established disposal procedures

5.1.7.9. The pharmacy shall implement manual or electronic stock management systems for available stock, dispensed and unfit for use medicines.

5.1.7.10. Stock rotation should be conducted on the "FIRST EXPIRY- FIRST OUT" (FEFO) or "FIRST IN - FIRST OUT" (FIFO) basis which shall include:

a) Regularly removing all expired items from the store and checking for near-to expiry medicines.

b) Marking all containers and boxes with the expiration date of the medicines.

c) Arranging stock according to FEFO or FIFO to facilitate stock rotation.

d) Placing medicines with the earliest expiration date in front /on top and those with the latest expiration date in the back/below.

e) Avoiding division of medicine stocks for the same products across different locations.

f) Recording the expiration date of every medicine during physical inventories.

g) Using a stock card, bin card or electronic recording system for stock management

h) Performing periodic stock reconciliation by comparing the actual and recorded stocks

5.1.7.11. The record of stock on hand and dispensed prescription only medicines shall be maintained to easily trace the disposition of any item.

5.1.7.12. The pharmacy shall implement procedures whereby a registered pharmacist shall reconcile quantities of narcotic drugs and psychotropic substances dispensed against the records. Any discrepancies shall be reported to the appropriate regulatory body.

5.1.7.13. The pharmacy shall receive medicines using standard receiving vouchers, which shall include the following information.

a) Generic and brand name of medicines received;

b) Unit of measurement and quantity

c) Name and address of manufacturer;

d) Dosage form and strength

e) Batch number

f) Manufacturing and Expiry dates;

g) Unit and total price;

h) Date received;

i) Name and signature of receiver; and

j) Address of the pharmacy.

5.1.7.14. The pharmacy shall use a standard stamp and seal for approving legal transactions.

5.1.8. Recording, reporting and documentations

5.1.8.1. The pharmacy shall develop and implement standard operating procedure for recording of procurement, stock management, recall, expired and damaged products, and disposal.

5.1.8.2. The pharmacy shall record products procured, stock status, recall, expired and damaged, and disposed of products immediately on the stock controlling cards (bin card, stock card or electronic system).

5.1.8.3. The pharmacy professionals shall properly fill the receiving, requesting, and dispensing documents.

5.1.8.4. The pharmacy shall maintain information for each patients with chronic illnesses using standardized information tracking formats and update patient medication profile during each refill visit (Annex D: Logbook for records of chronic illness medication registration)

5.1.8.5. The pharmacy shall document the following information labeled for easy retrieval

a) Invoices, receipts, daily sales records, stock control cards related with the stored, compounded and dispensed medicines
b) Dispensed prescriptions organized by date, month and year
c) Narcotic drugs and psychotropic substances prescription organized by date, month and year, and registration logbooks.
d) Valid copy of certificate of competence of the seller
e) Laws and guidelines
f) Medicine lists for pharmacy prepared by the authority

5.1.8.6. The pharmacy shall maintain narcotic drugs and psychotropic substances prescription paper and their registration book for at least five years and other medicines for two years.

5.1.8.7. The pharmacy shall report any stored, dispensed and stock discrepancies of narcotic drugs and psychotropic substances to the appropriate regulatory body.

5.1.8.8. The consumer shall have the right to know the exact price of a prescription before it is filled.

5.1.8.9. The pharmacy shall ensure that each consumer has the right to get a receipt having the following information about medicines dispensed.

a) Name of patient
b) Name and dose of medicine dispensed
c) Unit of measurement and quantity
d) Unit and total price
e) Date of dispensing
f) Signature of the dispenser
g) Address of the pharmacy

5.1.9. Safety and quality defect monitoring

5.1.9.1. The pharmacy shall establish and implement standard operating procedure for reporting of any adverse drug events of medicines in accordance with the national reporting systems designed by the authority.

5.1.9.2. The pharmacy professionals shall identify suspected adverse drug reactions, medication errors, quality defects, precaution and contraindication during dispensing.

5.1.9.3. The pharmacy professionals shall coordinate activities related to detection and reporting of adverse events.

5.1.9.4. The pharmacy professionals shall report to the authority or regional/city administration health regulatory bodies when he/she encounters defects associated with quality, safety, and efficacy of medicines.

5.1.9.5. All reports sent to the authority or regional/city administration health regulatory bodies shall be recorded and treated in strict confidentiality.

5.1.9.6. The pharmacy professional shall conduct physical inspection when receiving, stocking and dispensing of medicines to identify defective products.

5.1.9.7. The pharmacy professional shall implement and support the national medicine recall program.

5.1.10. Antimicrobial resistance prevention and containment

5.1.10.1. The pharmacy professionals shall understand the emergence and spread of antimicrobial resistance and be involved in the prevention and containment of it.

5.1.10.2. The pharmacy professionals shall influence behavior changes on prescribers, dispensers and community to ensure rational use of antimicrobial medicines.

5.1.10.3. The pharmacy professionals shall rationalize the use of antimicrobial medicines in line with the laws, guidelines and National Strategic Frameworks for prevention and containment of antimicrobial resistance.

5.1.10.4. The pharmacy professional shall promote and practice the Access, Watch and Reserve (AWaRE) classification of antibiotics to ensure rational use of medicines.

5.1.10.5. It is unlawful to dispense antimicrobial medicines without prescription.

5.1.11. Public health promotion

5.1.11.1. The pharmacy professionals shall ensure that any information or services related to health promotion offered to patients are safe, up-to-date and be aligned with relevant local and international guidelines.

5.1.11.2. The nature of health promotion activities in the pharmacy shall align with national medicine policy and scope of practices.

5.1.11.3. The pharmacist should provide screening and referral services for health conditions such as:

a) Hypertension
b) Diabetes Mellitus
c) Asthma
d) Dyslipidemia
e) Pregnancy testing
f) Malaria rapid test
g) STD rapid testing

5.1.11.4. The pharmacy professionals shall involve in behavioral and lifestyle modification services and shall include:

a) Sexual and reproductive health counseling
b) Oral health counseling
c) Smoking cessation counseling
d) Nutritional and physical-activity promotion
e) Healthy eating counseling
f) Weight management
g) Alcohol consumption advice
h) Explaining physiological harms of chat chewing
i) Immunization counseling
j) Traditional medicine use counseling

k) Women's health (e.g., preconception care)
l) Contraception and sexual health
m) Baby and child health
n) Drug misuse and abuse counseling and harm reduction

5.1.11.5. The pharmacy professional shall prevent the promotion of unregistered and off-label medicines information.

5.1.11.6. The pharmacy professional shall be trained on priority public health promotion initiatives before engaging on such services

5.1.11.7. Guidelines shall be issued to provide public health promotion activities.

5.1.12. Drug information center activities (if drug information center is established in the pharmacy)

5.1.12.1. The drug information center shall:

a) Provide an organized database of information on specialized medicines to meet healthcare practitioner's needs
b) Provide evidence-based and updated drug information to healthcare professionals, patients and the general community.
c) Monitor and evaluate the quality of drug information
d) Serve as a learning center about drug information to pharmacy, medical and health sciences students.
e) Support the promotion of clinical services and roles of pharmacy in various health-related fields.
f) Coordinate and support programs on population-based medication practices including developing guidelines, protocol, evaluation criteria
g) Engage in efforts to prevent adverse drug effects.
h) Conduct and monitor medication safety alerts from regulatory authorities, drug manufacturers, and other sources
i) Identify and manage alternative treatments and develop protocols on restrictive medication usage

5.1.13. Medicines waste management and disposal

5.1.13.1. The pharmacy shall develop and implement procedure for disposal of unfit for use medicines.

5.1.13.2. The pharmacy shall not store unfit for use medicines for more than six months, if not it shall report to the Regional/city administration health regulatory body.

5.1.13.3. Medicine wastes shall be disposed of in designated areas for disposal.

5.1.13.4. Medicine wastes shall be managed and disposed according to Medicine Waste Management and Disposal Directive and the procedures developed by the pharmacy.

5.1.13.5. Unfit for use medicines shall be clearly segregated, identified, recorded and stored separately before disposal or return to the supplier (Annex E).

5.1.13.6. The pharmacy professionals shall ensure disposal of medicines is conducted in a manner that protects and preserves the environment and prevent medicines due for disposal does not return into the population for use.

5.1.13.7. The pharmacy shall minimize the generation of medicine wastes.

5.1.13.8. The pharmacy professionals and other staff shall be trained and well informed on the risks of medicine wastes and their management.

5.1.13.9. Disposal of medicines wastes shall be supported by proper documentation as per national laws or the standards.

5.1.13.10. The pharmacy professionals and other staff shall use personal protective equipment during handling medicine wastes.

5.2. Premises

5.2.1. Design, Layout, and Location

5.2.1.1. The pharmacy shall be self-contained and secured with single point of entry and exit

5.2.1.2. The pharmacy shall be located a minimum of 100 meter radius far away from hospitals, health centers, specialty centers, and clinics.

5.2.1.3. The minimum distance between the proposed site for a pharmacy and other existing community pharmacies shall be a minimum of 100 meter radius.

5.2.1.4. The premise from which services are provided shall be safe, fit for purpose and well-maintained.

5.2.1.5. Construction of the premises shall prevent direct sunlight, dust, moisture, entry of insects, animals (especially rodents) or birds, and flooding.

5.2.1.6. The walls of the pharmacy shall be constructed and maintained from concrete, bricks and paint washable walls. Use aluminum board or bricks for internal partitions.

5.2.1.7. The design and layout of the pharmacy shall permit a logical flow of work, effective communication and supervision, and ensure effective cleaning and maintenance.

5.2.1.8. The design and layout of the pharmacy shall minimize the risk of errors, cross-contamination or mix up.

5.2.1.9. The pharmacy shall display a clear signboard bearing the pharmacy's name and working hours.

5.2.1.10. The pharmacy shall have the following rooms

a) Store room
b) Dispensing room
c) Compounding room (optional)
d) Counseling room
e) Drug information service shared with counseling room
f) Drug information center (optional)
g) Administrative office and changing room or area
h) Toilet with water
i) Waiting area

5.2.1.11. Floors, ceilings and walls shall be free of cracks and holes, discoloration, leakage, water stains and other signs of disrepair.

5.2.1.12. The pharmacy entrance, dispensing counter and doorways shall be accessible to people with disability.

5.2.1.13. The pharmacy shall have adequate lighting and ventilation.

5.2.1.14. The dedicated rooms and areas shall be labeled.

5.2.2. Security and safety

5.2.2.1. The pharmacy shall develop and implement safety and security procedures

5.2.2.2. The pharmacy shall be lockable to prevent an unauthorized entry.

5.2.2.3. The safety and security procedure shall be implemented for safety of both staff and medicines

5.2.2.4. A health and safety procedure shall be available, read and signed by all staff.

5.2.2.5. Working conditions shall be appropriate to protect the safety of staff working in the premises and comply with relevant legislation relating to safety in the workplace.

5.2.2.6. The pharmacy shall be equipped with a fire extinguisher, regularly checked and staff shall be familiar with the use of fire extinguishers

5.2.2.7. Electrical equipment shall be safe and maintained regularly. Care shall also be taken to avoid trailing wires across floors, work surfaces or sinks.

5.2.2.8. All chemicals containers shall be labeled with appropriate warnings (e.g. " Poison", "Flammable", "Radiation", etc.).

5.2.2.9. Combustibles/flammables shall be stored on a special or separate shelf.

5.2.2.10. First-aid materials shall be provided and staff shall be instructed on first-aid techniques, emergency care and the use of antidotes.

5.2.3. Environment in pharmacy premises

5.2.3.1. Storage of thermolabile medicines shall be as per manufacturer's storage instructions.

5.2.3.2. Refrigerators used for storing thermolabile medicine shall be calibrated regularly.

5.2.3.3. Medicines shall be protected from the adverse effects of light, heat, freezing or other temperature extremes and dampness.

5.2.3.4. All parts of the premises shall have suitable and effective means of heating or cooling, lighting and ventilation.

5.2.3.5. Background music or other broadcasts in the pharmacy shall not be played at such a volume so as to cause distraction, as per environmental standards.

5.2.3.6. The pharmacy premises shall be 100 meters radius far away from the premises of any other facilities that adversely affect the quality of medicines including public toilet with leakage and unhygienic, high dust, heat or smoke generating small & large scale industry, Garage, grinding mills, chemical industries, gas depot and waste disposal sites.

5.2.4. Sanitation and hygiene

5.2.4.1. The pharmacy shall have a cleaning procedure and schedule, and retain cleaning records.

5.2.4.2. All parts of the pharmacy premises and environments shall be kept clean especially floors, work surfaces and shelves.

5.2.4.3. Spillages shall be clean-up immediately.

5.2.4.4. Food and drink shall be kept out of the dispensing area and the refrigerator shall be strictly used for storing medicines.

5.2.4.5. There shall be a regular checking, cleaning and defrosting of the refrigerator

5.2.4.6. Direct contact between dispensing staff's bare hands and medicines shall be avoided.

5.2.4.7. The pharmacy professionals shall wear a neat, wrinkle free and well-repaired white gown while on duty at all times.

5.2.4.8. The gown color of pharmacy professionals and supportive staff shall be different.

5.2.5. Storage room

5.2.5.1. The storage room shall be dry, well ventilated and protected from direct sunlight and heat.

5.2.5.2. Storage room shall be self-contained and secure with a lockable door.

5.2.5.3. There shall be a designated area or room in the store room for expired, damaged or returned medicines.

5.2.5.4. The minimum size of the store room shall be 12 square meter with a minimum side of 3 meter

5.2.5.5. The ceiling height shall not be less than 2.6 m. In areas with consistently elevated temperature which is greater than 25 degree centigrade, the minimum ceiling height shall be 3m.

5.2.5.6. Storage room shall have sufficient shelving constructed from a s mooth, washable and impermeable material

5.2.5.7. The floor shall be smooth and easily washable, and constructed from cement, ceramic, epoxy or other related materials.

5.2.5.8. The wall shall be s mooth, and washable. It shall not be constructed from wood, corrugated sheet, mud or grass materials.

5.2.5.9. The ceiling shall be smooth, washable and heat resistant.

5.2.5.10. Medicines in the storage room shall be shelved a minimum of 20 cm above the floor, one meter wide between shelves and 25 cm away from the wall and 50 cm ceiling. If pallets are used, there shall be 20 cm above the floor, one meter between pallets and 25 cm away from the wall.

5.2.6. Dispensing room

5.2.6.1. The size of the dispensary shall reflect the volume of prescriptions dispensed and allow a safe and efficient flow of work and effective communication and supervision for the number of persons working in the dispensary.

5.2.6.2. The minimum area for the dispensing room shall be 25 square meters with a minimum side of 4 meters.

5.2.6.3. The minimum ceiling height shall not be less than 2.6m. In areas with consistently elevated temperature which is greater than 25 degree centigrade, the minimum ceiling height shall be 3m.

5.2.6.4. Dispensing counter shall not be less than 1.5meter far away from back shelf and 2.5 meter far away from the patient gate.

5.2.6.5. The dispenser counter shall have at least a width of 0.60 meter, height of 1.10 meter and length of 1m per dispenser with a total length of not less than 3.5 meters.

5.2.6.6. A waiting area with seating option shall be situated inside the dispensing room. The number of seating available in the waiting area shall depend on the number of patients expected to arrive at a time.

5.2.6.7. Narcotic drugs and psychotropic substances shall be kept separately in a fixed and lockable metal cabinet or shelf.

5.2.6.8. Access to the actual dispensing area shall be restricted to authorized personnel

5.2.6.9. Medicines in the dispensing room shall be shelved a minimum of 20 cm above the floor, one meter wide between shelves and 25 cm away from the wall and 50cm ceiling. If pallets are used, there shall be 20 cm above the floor, one meter between pallets and 25 cm away from the wall.

5.2.7. Compounding room (optional)

5.2.7.1. The pharmacy shall have a designated compounding room that avoids contamination and cross contamination.

5.2.7.2. The compounding room shall be neat, ventilated and appropriate for compounding activities.

5.2.7.3. The walls of the compounding room shall be finished from a smooth, washable and impermeable material, which is easy to clean and maintain in a hygienic condition.

5.2.7.4. There shall be a suitable and clean wash basin made of a smooth, washable and impermeable material for the compounding room and has a source of tap water and a closed drainage system.

5.2.7.5. The minimum area of the compounding room shall be 9 square meters with minimum side not less than 2.5 meters.

5.2.7.6. The compounding bench top shall be made of stainless steel, marble or similar acceptable material which is washable, impermeable, chemical resistant and waterproof material.

5.2.7.7. The compounding bench top shall not be made of wood, cement, corrugated sheet or plastic materials.

5.2.7.8. The compounding bench shall have at least a width of 0.75 meter, a total length of not less than 2 meters, and not be less than 1.5 meters far away from the gate.

5.2.7.9. There shall be a designated storage cabinet or shelf for labeling and raw materials.

5.2.8. Counseling room

5.2.8.1. The counseling room shall have a minimum area of 4 square meters with a minimum side of 1.5 meters, suitable for demonstrating the correct and safe use of specific medicines.

5.2.8.2. The counseling room shall maintain confidential conversation between pharmacists and clients about their medication and general health matters, and ensure privacy.

5.2.8.3. The counseling room shall be easily accessible and, where possible, be close to the dispensary.

5.2.8.4. Clear directions shall be provided if the counseling room is not close to the dispensing room.

5.2.8.5. The counseling room shall be designated to ensure privacy and minimize background noise as far as possible.

5.2.8.6. The counseling room shall be equipped with reference material, patient information leaflets and demonstration charts, kits and other demonstration material, registration book, chair and table.

5.2.9. Drug information service shared with counseling room

5.2.9.1 Drug information service shall be provided within the pharmacy and shared with the counseling room.

5.2.10. Drug information center (if drug information center is established)

5.2.10.1. The pharmacy shall establish a well-equipped drug information center with a minimum area of 12 square meters and minimum side length 3 meters.

5.2.10.2. The center shall have and additional office room for the staff of the drug information center.

5.2.11. Administrative office and changing room or area

5.2.11.1 The pharmacy shall have a dedicated area or room to perform office activities and changing of working attire.

5.2.12. Toilet with water

5.2.12.1. There shall be toilet room for the pharmacy, which may be shared with other facilities if the pharmacy is in a multipurpose building.

5.2.12.2. The toilet room shall have readily available potable water with hand wash basin, and soap and a closed drainage system.

5.2.12.3. The toilet facilities shall be kept clean and in good order.

5.2.12.4. The toilet room shall not be used for storage, and as a source of water for dispensing and compounding.

5.2.12.5. The toilet shall not have direct access to the store and dispensing rooms.

5.2.12.6. The toilet shall be clearly designated and labeled with arrows or images.

5.3. Professionals

5.3.1. The pharmacy shall be directed by registered and licensed pharmacist with a minimum:

a) three years of work experience as a pharmacist with bachelor or advanced degree in pharmaceutical sciences, or

b) Three years of work experience as a druggist or level IV pharmacy technician and additional one year as a pharmacist.

5.3.2. Any professional who has an advanced degree in pharmaceutical sciences without a bachelor degree in pharmacy shall not provide community pharmacy services.

5.3.3. The pharmacy shall have at least one additional licensed pharmacist or druggist/level IV pharmacy technician who works under the supervision of the technical manager.

5.3.4. The pharmacy shall have at least one registered and licensed pharmacist when it establishes a drug information center.

5.3.5. The pharmacy professional working in the drug information center shall have a minimum of bachelor degree in pharmacy and at least three years of work experience in pharmacy services.

5.3.6. The pharmacy professional shall not have mental illness, disabilities, alcohol, narcotic drugs, psychotropic substances, or other controlled substance addictions that impair his/her ability to perform his/her professional duties.

5.3.7. The technical manager shall perform his/her responsibilities autonomously. But in his/her absence, she/he shall delegate a pharmacy professional in writing who fulfills the minimum requirements to obtain a certificate of competence for not more than one month per year. This information shall be notified to the regional/city administration regulatory body. Delegation due to illness or maternity shall be in accordance with the country's labour law.

5.3.8. All staff working in the pharmacy shall undergo an annual medical check-up from a licensed health facility and keep the medical check-up reports in the pharmacy.

5.3.9. The pharmacy shall maintain documentation of staff educational credentials, valid professional licenses and training certificates.

5.3.10. The pharmacy professional on duty shall wear an identification badge at all times displaying his/her name, profession and title.

5.3.11. The pharmacy professionals shall be provided with current written job descriptions and oriented to their specific job responsibilities at appointment.

5.3.12. The job description shall include the title and grade of the position, job functions, job requirements, reporting mechanisms, and work environment.

5.3.13. The pharmacy shall provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff. The orientation program should at least include:

a) Sector related proclamation, regulations and directives.
b) Job duties and responsibilities
c) Sanitation and hygiene
d) Patient rights
e) Good dispensing practice and good compounding practices
f) Service provisions
g) Reporting requirements for adverse drug event, and narcotic drugs & psychotropic substances
h) Safety procedures

5.4. Products (Equipment and materials)

5.4.1. The pharmacy shall have appropriate dispensing, storage and compounding equipment and materials.

5.4.2. Adequate equipment and material that is suitable for all the operations that have to be carried out shall be available.

5.4.3. The pharmacy shall have continuous power supply.

5.4.4. The dispensing and storage device shall be calibrated, maintained, kept clean at all times and be in good repair.

5.4.5. Compounding equipment shall be c alibrated regularly and documentation showing proof of calibration and servicing shall be maintained.

5.4.6. Countertops and shelves shall be finished in a smooth, washable and impermeable material which is easy to maintain in a hygienic condition.

5.4.7. Dispensing and storage equipment and materials shall include:

a) Counting devices for tablets and capsules
b) Tablet cutter
c) Stainless steel spoon
d) A refrigerator equipped with a maximum and minimum thermometer which is capable of storing products at temperatures between 2°C and 8°C. Pharmaceutical grade refrigerators should be recommended.
e) A suitable range of dispensing containers with separate sets for internal and external use.
f) Secure fixed metal cabinet or s helf with lock and key for narcotics drugs and psychotropic substances.
g) Wall thermometer and hygrometer or thermo hygrometer for both storage and dispensing room.
h) Ventilator or air conditioner as appropriate.
i) Fire extinguisher.
j) First aid kit
k) Weighing balance with height measurement (optional)
l) Blood pressure (BP) apparatus (optional)
m) Blood glucose measuring equipment (optional)
n) Pulse oxymeter (optional)
o) Pregnancy test kit (optional)
p) Scientific calculator and scissor
q) Fixed telephone or mobile phone
r) Computer (s)
s) Shelves and pallets
t) chairs for waiting area

5.4.8. The phar macy s hall have reference m aterials (soft or har d c opy version), i ncluding Martindale, Pharmacology textbooks, Medical dictionary, relevant proclamation, Community pharmacy medicine lists, National standard treatment guideline, National medicine formulary, National good dispensing manuals, Demonstration charts, kits and other demonstration material; and Reporting formats, transcription paper, bin card, stock card, registration books

5.4.9. The drug information center (if established) shall have the following products

a) Furniture (shelves, tables and chairs).
b) Telephone line

c) Internet access
d) Computer and software
e) Printers and duplication machine
f) Drug databases: Access to reliable databases and references such as Micromedex, Lexicomp, Clinical Pharmacology, or Up to Date.
g) Drug information center standard operating procedures
h) Reference materials (primary, secondary and tertiary sources).

5.4.10. Compounding equipment and material shall include, if compounding is performed in the pharmacy:

a) Working bench with upper part made of marble or stainless steel
b) Dispensing balance (Analytical balance),
c) Mortar and pestle (glass or porcelain) not less than 250ml
d) Stainless steel hot water bath (electrical) with four or more openings
e) Hot plate (electrical)
f) Shaker or stirring rods (glass or plastic) of different length and thickness
g) Spatula (stainless steel, plastic, flexible or non-flexible)
h) Ointment tile or slab
i) Wash bottle
j) Funnel (glass or poly ethylene)
k) Beaker (different sizes)
l) Test tubes of different sizes
m) Graduated cylinders (different volumes)
n) Weighing paper (normal, grease-proof for semi solids)
o) Weighing dishes (plastic, aluminum, stainless steel)
p) Evaporating dish
q) Volumetric flask
r) PH meter
s) Alcoholometry
t) Thermometers
u) Purified water
v) Disposable gloves and masks
w) Labeling and packing materials
x) Electrical light or lamp aa

Annex A
(Informative)
Standard Prescription

PRESCRIPTION PAPER Code_____

Institution Name: _____Tel. No… ……

Patient's full Name: _____

Sex: ___ Age:___ Weight: _____ Card No. _____

Region: _____Town _____ Woreda_____Kebele _____

House No. ____ Tel. No: _____☐ Inpatient ☐Outpatient

Diagnosis, if not ICD _____

Medicine N ame, S trength, Dosage F orm, D ose, Frequency, D uration, Q uantity, H ow t o us e & other information	Price (dispensers use only)
℞	
Total Price	

Prescriber's Dispenser's

Full name _____ _____

Qualification _____ _____

Registration #_____ _____

Signature _____ _____

Date: _____ _____

See overleaf

Please Note the Following Information
Prescriptions:

- May valid only if it has the seal of the health institution.
- filled and blank are legal documents, treat them as fixed assets

- written and verbal information to the client complement one another

The prescriber:

- Medicine treatment is only one of the treatment options
- write the prescription correctly and legibly
- diagnosis and other parts of the prescription have to be complete
- abbreviations are NOT recommended
- please accept prescription verification call from the dispenser

The Dispenser:

- check legality of the prescription
- check completeness and accuracies before dispensing
- check for whom the medicine is being dispensed: actual client or care taker
- if in doubt about the contents of the prescription; verify with the prescriber
- containers used for packaging must be appropriate for the product
- labels of drugs should be clear, legible and indelible
- Medicines should be dispensed with appropriate information and counseling
- keep filled prescriptions at least for 3 years

Minimum drug label information should include the following:

- Patient name
- Generic name, strength and dosage form of the medicine
- Dose, Frequency and Duration of use of the medicines
- Quantity of the medicine dispensed
- How to take or administer the medicine?
- Storage condition

Annex B

(Informative)

Transcription paper

Ser. No. _____
Standard Transcription paper copy
Institution Name: _____Tel. No… ……
Prescription PAPER Code/ Ser. No._____ Transcription PAPER Code /Ser. No. _____
Institution Name: _____Tel. No… ……
Patient's full Name: _____
Sex: ___ Age: ___ Weight: _____ Card No. _____
Region: _____Town _____ Woreda_____ Kebele _____
House No. ____ Tel. No: _____ ❒Inpatient ❒Outpatient
Diagnosis, if not ICD _____

Drug Name, Strength, Dosage Form, Dose, Frequency, Duration, Quantity, Route of administration& other information	Price (dispensers use only)
℞	
Total Price	

Transcriber's	**Dispenser's**
Full name _____	Full name _____
Qualification _____	Qualification _____
Registration # _____	Registration _____
Signature _____	Signature _____
Date: _____	Date: _____

See overleaf

Please Note the Following Information

1. Prescriptions

1.1. Are valid only if it has the seal of the health institution

1.2. Filled and blank are legal documents, treat them as fixed assets

1.3. Written and verbal information to the client complement one another

2. The prescriber

2.1. Never allow others to use Rx issued under your custody

2.2. Drug treatment is only one of the treatment options

2.3. Write the prescription correctly and legibly

2.4. Diagnosis and other parts of the prescription have to be complete

2.5. Name of medicine should not be abbreviated.

2.6. Please accept prescription verification call from the dispenser

2.7. If dosage must be repeated by the same Rx describe so and sign

3. The Dispenser –

3.1. check legality of the prescription

3.2. check completeness and accuracies before dispensing

3.3. check for whom the medicine is being dispensed: actual client or caretaker

3.4. if in doubt about the contents of the prescription; verify with the prescriber

3.5. Containers used for packaging must be appropriate for the product

3.6. Labels of drugs should be clear, legible and indelible

3.7. Drugs should be dispensed with appropriate information and counseling

3.8. keep filled prescriptions at least for 2 years

4. Minimum drug label information should include the following:

4.1. Patient name

4.2. Generic name, strength and dosage form of the medicine,

4.3. Dose, Frequency and Duration of use of the medicines,

4.4. Quantity of medicine dispensed

4.5. How to take Route of administration

4.6. Storage condition

Annex C

(Informative)

Compounding Registration Book

Name of pharmacy _____Name of Source Hospital/Health center/Clinic: _____

Name of the patient: _____Age: _____Sex: _____Card No.____

Batch number/control number_____ Batch total quantity _____

S. No.	Name of ingredients used	Strength	Quantity
1			
2			
3			
Summarized description of the steps followed for the preparation			
Beyond use Date: ……			
Prepared by: Name _____ Signature:_____Date: _____			
End product control before release (to be filled by dispenser)			

Parameters	***Comment or tick***
Physical appearance	
Appropriateness of the package	
Appropriateness of the label	
Any other thing performed as quality control measure	

Dispensed by: Name _____ Signature: _____date: _____

Patient Signature: _____

(The patient/caregiver/relative who received the product should sign here for confirmation)

Annex D

(Informative)

Logbook for record of chronic illness mediation registration

SN	Patient Name	Phone Number	Card Number	Diagnosis	Name o f health facility	Drug Name	Strength	Dosage form	Duration	Dispensing date	Signature o f Pharmacist	Signature of Patient

Annex E

(Informative)

Medicines Waste Registration Book

SN	Description of Medicines W astes (generic & b rand name, strength and dosage form)	Unit Type and Size	Quantity	Batch Number	Expiry Date	Reason f or Disposal (expired, damaged, spilled, etc.)	Manufacturer/ Supplier name	Store Location	Purchase value

Bibliography

Food and Medicines Administration Proclamation No. 1112/2019

Regional regulations and directives

Good pharmacy practice, Joint FIP/WHO guidelines on GPP: standards for quality of pharmacy services

Good pharmacy practice in South Africa, 4th Ed, 2010

Medicine retail outlets licensure and control model directive, EFMHACA, 2013

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INSTITUTE OF ETHIOPIAN STANDARDS

Organization and Objectives

The Institute of Ethiopian Standards (IES) is the national standards body of Ethiopia. IES is re-named by the proclamation number 1263/2021, from Ethiopian Standards Agency (ESA) to Institute of Ethiopian standards, with the mandate given by the regulation Number, 193/2010 and proclamation number, 1263/2021.

IES's objectives are:

- Develop Ethiopian standards and establish a system that enable to check whether goods and service are in compliance with the required standards,
- Facilitate the country's technology transfer through the use of standards,
- Develop national standards for local products and services so as to make them competitive in the international market.
- Conduct standards related research and provide training and technical support.

Ethiopian Standards

The Ethiopian Standards are developed by national technical committees which are composed of different stakeholders consisting of educational and research institutes, governmental organizations, certification, inspection, and testing organizations, regulatory bodies, consumer association etc. The requirements and/ or recommendations contained in Ethiopian Standards are consensus based that reflects the interest of the TC representatives and also of comments received from the public and other sources. Ethiopian Standards are approved by the National Standardization Council and are kept under continuous review after publication and updated regularly to take account of latest scientific and technological changes.

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